Food

Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling

Contains Nonbinding Recommendations

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Office of Nutritional Products, Labeling and Dietary Supplements
Food Labeling and Standards Staff, HFS-820
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2375 (Updated phone: 240-402-2375)
http://www.cfsan.fda.gov/guidance.html

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Guidance for Industry and FDA [1]
Dear Manufacturer Letter Regarding Food Labeling

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Dear Manufacturer:

The Food and Drug Administration (FDA) is reminding manufacturers and distributors of conventional food products about the different types of labeling claims available for use on conventional food products and how these claims are regulated by the Agency. Currently, claims that appear on conventional food labels and labeling generally fall into the following categories: health claims, structure/function claims, nutrient content claims, and dietary guidance.

A health claim is a claim that describes the relationship between a substance (food or food component) an a disease or health-related condition (21 CFR 101.14(a)(1)). Health claims are limited to claims about disease risk reduction and cannot be claims about the cure, mitigation, treatment or prevention of disease. The latter claims are drug claims under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food: (1) FDA issues a regulation authorizing a health claim that meets the significant scientific agreement standard set forth in the 1990 Nutrition Labeling and Education Act (NLEA); (2) FDA prohibits or modifies, by regulation, a health claim within 120 days after it has received a health claim notification under the 1997 Food and Drug Administration Modernization Act (FDAMA), which permits health claims based on an authoritative statement from a scientific body of the United States (U.S.) government with official responsibility for public health protection or research directly related to human nutrition or the National Academy of Sciences or any of its subdivisions (in the alternative, a U.S. District Court in an enforcement proceeding may find that the requirements of sections 303 or 304 of FDAMA have not been met); and (3) FDA issues a letter of enforcement discretion for qualified health claim

pursuant to the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* which provides for qualified health claims where the strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. These types of health claims must be qualified to ensure accuracy and non-misleading presentation of information to consumers. Although FDA's "enforcement discretion" letters are issued to the petitioner who requested the qualified health claim, the qualified health claims are available fc use on other products that meet the enforcement discretion conditions specified in the letter.

The following is an example of a health claim that meets the significant scientific agreement standard abou the relationship between sodium (a substance) and high blood pressure (a disease or health-related condition): "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors." In comparison, the following is an example of a drug claim: "We've loaded our product with nature's best cold fighters." See http://www.cfsan.fda.gov/~dms/lab-ssa.html; http://www.cfsan.fda.gov/~dms/labfdama.html and http://www.cfsan.fda.gov/~dms/lab-qhc.html for additional information about health claims and qualified health claims.

"Structure/function" claims can be made on the labels of conventional foods. These claims describe the role of substances intended to affect the normal structure or function in humans (21 CFR 101.93), for example, "calcium builds strong bones." In addition, structure/function claims may characterize the means by which substances act to maintain such structure or function, for example, "fiber maintains bowel regularity" or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure function claims may also describe a benefit related to a nutrient deficiency disease (like Vitamin C and scurvy), as long as the statement also tells how widespread such disease is in the U.S. Such claims may not explicitly or implicitly link the relationship to a disease or health-related condition. We point out that structure/function claims on conventional foods can be made without FDA review or authorization before use, but they must be truthful and not misleading and the claims must derive from the nutritional value of the product. See http://www.cfsan.fda.gov/~dms/labstruc.html for additional information about structure/function claims.

Nutrient content claims (21 CFR 101.13) describe the level of a nutrient in a food using terms such as *free*, *high* and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced* and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) may be used to describe any amount of a nutrient present. However, a statement such as only "200 mg of sodium" characterizes the level of sodium as being low and would have to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement that it does not comply with the claim. Most nutrient content claim regulations apply only to those nutrients or substances that have an established Daily Value (DV). The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as *high* or *low*, are used consistently for all types of food products and are meaningful to consumers. The term *Healthy* has been defined by a regulation (21 CFR 101.65(d)) as an implied nutrient content claim that characterizes a food that has "healthy" levels of total fat, saturated fat, cholesterol, other nutrients and sodium. FDA exercises its oversight in determining which nutrient content claims may be used on a labe or in labeling for a food by two means: (1) FDA issues a regulation authorizing a nutrient content claim afte FDA's careful review of the scientific evidence submitted in a nutrient content claim petition, and (2) FDA prohibits or modifies, by regulation, a nutrient content claim within 120 days after it has received a nutrient content claim notification under FDAMA, which provides for nutrient content claims based on an authoritative statement from a scientific body by the U.S. government with official responsibility for public health protection or research directly related to human nutrition or the National Academy of Sciences or any of its subdivisions (in the alternative, a U.S. district court may find that the requirements of sections 303 or 304 of FDAMA have not been met). See http://www.cfsan.fda.gov/~dms/lab-nutr.html and http://www.cfsan.fda.gov/~dms/labfdama.html for additional information on nutrient content claims.

"Dietary" guidance statements can also be made on food labels. While health claims describe the relationship between a substance (specific food or food component) and a disease or health-related condition, dietary guidance statements do not contain both elements (see 58 FR 2478 at 2487, January 6, 1993). Dietary Guidance statements tend to focus on general dietary patterns, practices and recommendations that promote health. Typically "dietary guidance" statements make reference to a category of foods and not a specific substance. An example of a dietary guidance statement is: "Carrots are good for your health." Dietary guidance statements can be made without FDA review or authorization before use but the statements must be truthful and non-misleading.

FDA also recognizes that information available through the Internet, including those websites that provide truthful and non-misleading information about conventional food products can serve a valuable and useful function. FDA addressed the issue of food product labeling and the Internet in a November 1, 2001 letter t the Washington Legal Foundation, which is available at http://www.cfsan.fda.gov/~dms/labwww.html. In certain circumstances, information that is disseminated over the Internet by, or on behalf of, a regulated company meets the definition of labeling in section 201(m) of the Act and is subject to the requirements of the Act. For example, if a company were to promote a regulated product on its website and allow

consumers to purchase the product directly from the website, the website is likely to be "labeling." As another example, if the label for a product contained a statement that referred the consumer to a specific website for additional information about a claim for the product, the website is likely to be "labeling." The websites, in these cases, are considered written, printed, or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product.

Because accurate food labeling information can assist consumers in making healthy nutritional choices, FDA recommends that manufacturers and distributors continue to include appropriate claims on their food products and that they ensure that these claims are consistent with FDA's current laws and regulations. In addition, all manufacturers and distributors are reminded to review your Internet sites and to make sure that the information presented on those sites is also consistent with FDA's current laws and regulations.

Sincerely,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration

[1] This guidance has been prepared by Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, at the Food and Drug Administration (FDA).

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